

A New Endoprosthesis with Sensing Capability

Isa C.T. Santos, Alexandra Sepúlveda, Luís A. Rocha and João Manuel R. S. Tavares

Abstract— An aneurysm is a severe health condition with high impact in human life. One of its current treatments is endovascular aneurysm repair, a minimally invasive surgery in which a stent-graft is guided, from the femoral artery to the affected segment, in order to prevent wall rupture. Stent-grafts are endoprosthesis composed of a metallic scaffold and a polymeric covering membrane. While early devices were made from stainless steel stents and woven polyester grafts, nowadays other materials are being used. The device's performance has been improved by the introduction of new materials; nevertheless, literature shows that more can be done. This article reviews the design of some thoracic “home-made” stent-grafts as well as the commercial devices available both in Europe and in the USA. Additionally, future trends concerning the development of this type of devices are presented, including the design of a new endoprosthesis with an embedded flexible pressure sensor.

Keywords— Aortic aneurysm, stent-graft, biomedical device, design, flexible pressure sensor

I. INTRODUCTION

An aneurysm, Fig. 1, can be defined as a permanent and irreversible localized dilation of an artery, having at least a 50% increase in diameter compared with the healthy one [1].

In spite of the fact that modern treatment of thoracic aortic aneurysm's (TAA) has started in the early 1950's, it had to wait until the 1990's to be revolutionized by the introduction of thoracic endovascular repair (TEVAR) [2]. This procedure is a minimally invasive surgery in which a stent-graft is guided from the femoral artery to the affected segment in order to prevent wall rupture by the elimination of the blood circulation in the aneurysm intra-sac.

A stent-graft is an endoprosthesis composed of a metallic scaffold and a polymeric covering membrane. The first thoracic device was made from stainless steel stents and a woven polyester graft but, currently, other materials, namely nitinol and ePTFE, are used. The introduction of new

materials has allowed designing devices with smaller profiles and better mechanical resistance. Nonetheless, literature shows that more can be done, like the introduction of drug delivery mechanisms and the verification of the stent-graft structural integrity.



Fig. 1. Representation of a normal artery (on the left), a fusiform aneurysm (on the centre) and a saccular aneurysm (on the right)

II. “HOME-MADE” STENT-GRAFTS

In 1994, Dake and colleagues [3], in their first report of TEVAR, custom-designed a stent-graft for each patient. Summarizing, they used stainless steel sinusoidal shaped stent elements to form a self-expanding cylindrical metallic framework, which was covered by a woven polyester graft (Dacron). The attachment of the graft to the stent was made using polypropylene sutures. Like Dake, other authors, such as Cambria [4] and Moon [5], custom-made stent-grafts using the same materials. Kato [6] and Won [7] used the identical kind of stent, but covered with ePTFE.

It is well known that, when compared with commercial devices, these stent-grafts had large caliber delivery systems, lack of flexibility, segmented design prone to kinking in curved aortic segments and the proximal deployment was inaccurate.

In his work, Inoue [8] constructed a branched stent-graft with woven polyester fabric cylinders, supported in the outside by multiple rings of extra flexible nickel titanium wire covered by Dacron filaments. In spite of the advantages pointed out, a problem that needed to be solved was related to the large profile of the branched stent-graft.

The Matsui-Kitamura (MK) stent-graft described by Sanada [9] had a different construction. Its framework was a spiral wound from a single nitinol wire and then covered with a seamless, cylindrical woven graft made of a thin polyester fabric. The graft was attached to the stent by polypropylene sutures and platinum markers in both ends were incorporated to ensure radiopacity. The major advantages pointed out include its flexibility, distinctive curved configuration, shape memory, and small profile when

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III. COMMERCIAL STENT-GRAFTS

While in the USA there are only three FDA-approved thoracic stent-grafts, in Europe more devices are available [10], Table 1. They differ in respect of the materials used, the design, the manufacturing processes and even the fixation and deployment techniques making possible the selection of the appropriate model for each patient and/or pathology [11].

All commercial thoracic stent-grafts have in common the fact of being self-expanding. Regarding the shape, they can either be tubular or present a maximum taper of 4 mm. The most common fixation technique is friction fit (radial force exerted due to oversizing), but there is at least one model, the Zenith TX2, that uses hooks (or barbs) instead.

TABLE I
STENT-GRAFTS COMMERCIALY AVAILABLE
IN EUROPE AND IN THE USA

Name	Manufacturer	Availability	
		Europe	USA
Gore Tag	W.L. Gore, Inc., Flagstaff, Arizona, USA	X	X
Talent Thoracic	Medtronic, Inc., Santa Rosa, California, USA		X
Zenith TX2	Cook Medical, Bloomington, Indiana, USA	X	X
E-Vita thoracic	Jotec, Hechingen, Germany	X	
Relay	Bolton Medical, Sunrise, Florida, USA	X	
TAArget	LeMaitre Vascular, Burlington, Massachusetts, USA	X	
Valiant	Medtronic, Inc., Santa Rosa, California, USA	X	

Only the stents of the Zenith TX2 are made of stainless steel, the other endoprostheses use nitinol. If the grafts are made of polyester, they are woven and the stents are sutured to them. On the other hand, as in the case of the Gore Tag and the TAArget, if ePTFE is used, the grafts are extruded and the stents are attached to the graft using a thermal process. The position of the metallic structure regarding the graft varies: it can be inlayed, outside the graft or inside.

Usually, the devices' bodies are fully stented with diamond shape stents (E-Vita thoracic) or sinusoidal ones and the proximal and distal ends may present different configurations.

IV. FUTURE TRENDS

The stent-grafts of the future will have fewer components and use different materials. For example, Kuribayashi [12] described the origami stent-graft, a single component device that employs the paper folding patterns used in the Japanese art of origami to fold it. Rigberg [13] proposes to reduce the diameter of the endoprostheses replacing currently used grafts by a thin-film Nitinol (NiTi).

Currently, after TEVAR, life-long surveillance is required but, since the existing protocol is not perfect, new technologies are being investigated and the most promising technique identified thus far is remote pressure sensing [14]. To date, the Impressure Sensor (Remon Medical Technologies, Israel) and the CardioMems EndoSure Wireless AAA Pressure Sensor (CardioMems, Inc, USA) have been evaluated and can measure both the systolic and diastolic pressures within the residual aneurysm sac at any given point in time [14].

V. NEW ENDOPROSTHESIS

Based on the design of current stent-grafts, we are developing a new device with an embedded flexible pressure sensor with passive telemetry. The use of a flexible substrate will enable the conformability of the sensor to the stent-graft and thus the aorta.

The sensor under development uses a passive telemetry system, based on an implantable LC resonant network. A circuit representation of the sensor and reader, using the transformer model (parasitic capacitance are not included), is presented in Fig. 2.

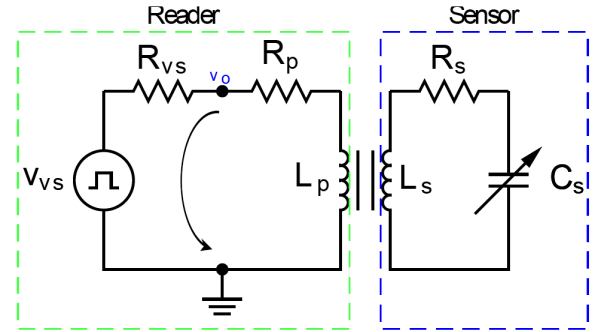


Fig. 2. Telemetry circuit

If the transformer is replaced by its T model, the following expression for the oscillating frequency is obtained:

$$f_{osc} = \frac{1}{2\pi\sqrt{(1-k^2)L_sC_s}} \quad (1)$$

The system oscillation frequency was chosen to operate in the frequency band from 12.5 MHz to 20.0 MHz allocated specifically for medical applications. This frequency band presents additional advantages, unlike low frequencies of operation, since the inductors and capacitors require small dimensions and therefore small sensors' area.

The realization of a pressure sensor and inductor to be incorporated in a stent-graft give raise to several challenges. Passive telemetry solves the power and communication constraints imposed by implantable devices, but the sensor platform needs to be thin (must fit inside the catheter without diameter increase) and extremely flexible (must cross a tortuous path till the deployment site). In order to address these challenges, a new fabrication process is being developed.

The proposed fabrication process is based on flexible thin bio-compatible substrates, where conductive elements are introduced for the development of the capacitive pressure sensor and inductor. The thin flexible substrate is made of polydimethylsiloxane (PDMS) and SU-8 (photoresist resin) molds are used to define the required geometry, Fig. 3.



Fig. 3. Molds made of polydimethylsiloxane (PDMS)

Two different approaches are being pursued to manufacture the electric components (the capacitor and the inductor). The first uses nano-engineered Aligned Carbon Nano-Tubes (ACNT) where a very good dimensional control is possible, Fig. 3, while the second approach will use injected conductive inks.

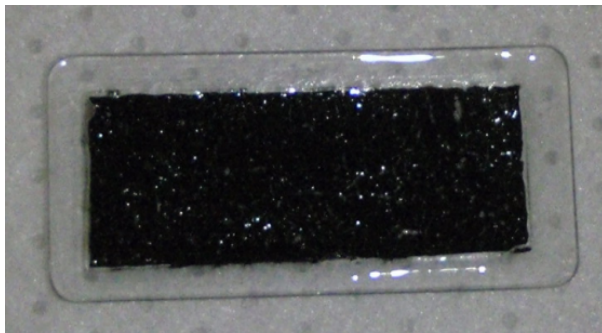


Fig. 3. Nano-engineered Aligned Carbon Nano-Tubes (ACNT)

Both methodologies are under development. The use of ACNT technology requires improvements in the growth control of the carbon nano-tubes and enhancement of the electric conductivity of ACNT embedded polymeric matrixes. Printing the components requires developments on conductive inks, in order to achieve enough conductivity and adherence to PDMS. In both cases, the mechanical and electric behaviour of the flexible film needs further studies.

A clear advantage of the proposed technologies, besides the associated low cost, is the possibility to integrate several pressure sensors around the sent-graft, enabling pos-endovascular studies of the aneurysm that are not currently possible.

VI. CONCLUSION

Literature denotes that current state-of-the-art on stent-grafts is at a mature stage and indicates that in the future endoprosthesis will include sensing capabilities.

This paper proposes a new endoprosthesis with an embedded flexible pressure sensor. However, before success is achieved further work is needed, namely the study of the best measurement location that can be a good indicator of complications and a more thorough analysis about the cost/benefit that such a device will represent for patients, doctors and medical devices manufacturers

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